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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/457,709 | 12/10/1999 | RICHARD J. MELKER | U5583.0000/P | 7980 |

24998 7590 06/19/2003

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| EXAMINER |
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WEISS JR, JOSEPH FRANCIS

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3761

DATE MAILED: 06/19/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/457,709

Applicant(s)
Meiker et al.

Examiner
Joseph Weiss

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 21, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-85 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 May 03 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 37-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanesaka (US 5042470) in view of Heinonen (US 5649531) & Haluszka et al, "Whole Body Plethysmography".

In regards to claims 37-85 Kanesaka substantially discloses the instant application's claimed invention to include the provision of a ventilator system (1/5) that contains a control device (Col. 4 lines 15-32, note the teaching of inputting of patient data into device that will facilitate ventilation, i.e. to control the device, therefore one of ordinary skill in the art would reasonably conclude that the device has a means for controlling its operation), with a means for

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inputting a data (note col. 4 lines 17-20) that provides ventilation to a patient and that calculates ventilatory parameters utilizing such data which includes data that only represents height (i.e. does not put in a mixed variable such as patient surface area based upon height & weight), but does not explicitly disclose that the data is input in the raw form and that the control device renders the calculation of such data into the necessary ventilatory parameters. However, Heinonen discloses such raw data input with the control device rendering the respiratory ventilation control values (col. 8 lines 19-40). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Heinonen and used them with the device of Kanesaka. The suggestion/motivation for doing so would have been to relieve the operator of the burden of rendering the calculations and also minimizing the potential for human error by having the control device execute the calculations instead of the operator. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose solely using only patient height. However, Haluszka discloses such (See the 5th paragraph on the first page of the English language abstract that starts with "It

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was stated”) The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application’s invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Haluszka and used them with the suggested device. The suggestion/motivation for doing so would have been to because patient body length alone can function as a sufficient ventilatory parameter/limitation predictor and all other raw data patient inputs improve correlation very little or are without practice influence (See paragraph 5 of the English language abstract of Haluszka). Therefore it would have been obvious to combine the references to obtain the instant application’s claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Claims 38-47 define a plurality of ventilation parameters which are disclosed by Kanesaka (note col. 4 lines 15-32) as modified by Heinonen and/or Haluszka (note the tables and materials/methods sections) and/or such parameters would be mere obvious variables that one of ordinary skill in the art would appreciate as necessary to carry out any ventilatory methodology.

The balance of the claims 48-85 appear to be substantially equivalent in scope to claims 37-47 and are therefore rejected by the suggested device of Kanesaka, Heinonen & Haluszka as noted above which is herein incorporated by reference. With respect to the alarms of claim 66 and those claims that set forth the calculation/determination of a “ventilatory limit” note Kanesaka

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(Col. 4, line 5 et seq) which teaches a plurality of alarms which are responsive to the manually set ventilation parameters disclosed at col. 4, lines 16 et seq; these same parameters of the suggested device of Kanesaka, Heinonen & Haluszka are readable upon applicant's set forth "ventilatory limits" as one of ordinary skill in the art would appreciate such limits to be merely the points of the derived values wherein safe/proper ventilation would not be affected and as such the operator/user should be notified and the control should respond/adjust ventilation.

Response to Arguments

4. Applicant's arguments filed 21 May 03 have been fully considered but they are not persuasive.

In regards to the issue of obviousness, applicant's amendment is proper and responsive, but does not resolve the issue, therefore the rejection is maintained as noted above and modified only to the extent necessary in response to applicant's amendments. A response to the arguments is noted below.

Generally:

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111© because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of

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the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Specifically:

In regards to the non-analogous art argument, **references are to be read in their entirety and not dissected and fragmented and then make broad generalizations about the content of the reference based merely upon such fragments.** The reference of Haluszka is for **RESPIRATORY** medical evaluation and examination and establishes the premise in the field, that applicant asserts as his inventive basis, that body length alone is a key indicator of respiratory parameters (note the translated text in the summary noted by the rejection). **Thus the reference squarely sits in the respiratory arts. Applicant is not claiming a device that divines the body length of a user, but merely used the input of data gathered from an evaluation of the patient for respiration therapy/support,** hence even on the erroneous distinction applicant asserts as the basis of non-analogous art argument the references are analogous, i.e. problem solving.

In regards to applicant's assertion that the reference does not disclose deriving ventilation parameters from height alone, the examiner notes the following:

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1-The title of the reference is “Application of Whole Body Plethysmography in the examination of Children’s LUNGS”

2-Lungs are part of the pulmonary system, the various measurements of lungs being a critical set of ventilation parameters.

3-The term Plethysmography means measuring volume and changes in the volume of lungs, lung volume is a ventilation parameter.

4-Haluszka is replete with recitations of lung volume measurements, that what the entire paper is about.

5-Haluszka, after gathering, reviewing and analyzing all his plethysmography data from the study group draws the conclusion that “body height was the best predictive variable for all measured parameters. Adding weight and age to height in the multiple regression improved correlations yet very little, but other anthropometric measures were practically without influence.” One of ordinary skill reading this conclusion would appreciate that height alone is the best predictor. That weight and age add very little to change or influence the predictive qualities of height alone as a ventilation parameter predictor and that all other variables add nothing. Thus by the plain language of the reference’s conclusions when read in its entirety by one of ordinary skill in the art would reasonably conclude that height alone is the best predictor of ventilation parameters.

The examiner thanks applicant for the partial translation of the Haluska reference.

However, usage of the term Plethysmography alone would be sufficient for one of ordinary skill in the respiratory arts to understand and appreciate the clarity of logic that the rejection is based

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upon. Rejections are intrinsic evidence and are thus written to the level of ordinary skill in the art. However, despite this usually sufficient baseline of communication, evidence to support the basal logic of the rejection that would be self-evidence to one of ordinary skill in the art is now presented for applicant edification. Applicant appears to base his argument of the false premise that the phrase "ventilation parameter" is a talisman of some sort, which cannot be arrived at via Plethysmography and thus distinguishes it from any parameter that can be derived from a Plethysmographic procedure. Applicant presents no evidence of this talisman status of the phrase "ventilation parameter." Applicant presents no definition that excludes Plethysmography based determinations of ventilation parameters. Thus the term "ventilation parameter" is given its plain meaning, and during prosecution its broadest reasonable interpretation. That interpretation is any parameter or "value" that one of ordinary skill in the art would use to set/delivery pulmonary ventilatory support to a user. The distinguished Treatise "Principles and Procedures of Mechanical Ventilation" by Dr. Martin J. Tobin states on page 172 first column under the subtitle "Pulmonary Mechanics Measurements" that such pulmonary mechanical parameters as airway resistance, pulmonary and respiratory system compliance, intrinsic PEEP (positive expiratory end pressure), occlusion pressure, and work of breathing are derivable by using a plethysmograph. These pulmonary mechanical measurements are respiratory parameters. Class 128/204.18 - 206.26 is replete to the point of being TNTC (Too Numerous To Count) of incidents in references where they are used as a "ventilation parameter." Applicant may wish to review the current art in the file or perform their own search of these sub classes to satiate their concern that

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Plethysmography cannot derive ventilatory parameters. For these same reasons the Haluszka reference is definitively relevant art in the instant case, i.e. the respiratory arts.

Usage of the legal phrase "one of ordinary skill in the art" in conjunction with the header 35 USC 103 inherently means the rejection is one of obviousness and not anticipation. The logic of applicant's arguments about the rejection are valid only if addressing an anticipation rejection, which this action does not contain.

In regards to reasons to combine to assist applicant is understanding the reasoned basis as noted in the rejection, please note the base reference discloses the use of height and Haluszka teaches use of height as the best indicator of ventilation parameters. **Hence one of ordinary skill in the art when reading the two references in their entirety would appreciate that use of height alone is sufficient to establish ventilation.**

Furthermore, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves **or in the knowledge generally available to one of ordinary skill in the art.** See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Regarding the isolated fragment of the Haluska reference that applicant asserts indicates that height cannot serve as a respiratory parameter, the examiner cites the document in its entirety

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and which in the end came to the ultimate conclusion that height can and does serve as they most critical input for determination of respiratory parameters and which one of ordinary skill in the art would conclude can be used alone to determine a respiratory parameter.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. F. Weiss

June 11, 2003



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